IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UPSHER-SMITH LABORATORIES, LLC,

Plaintiff,

v.

ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LTD.,

Defendants.

Civil Action No. _____

[redacted]

PUBLIC VERSION FILED:
SEPTEMBER 14, 2021

COMPLAINT

Plaintiff Upsher-Smith Laboratories, LLC, as successor in interest to Upsher-Smith Laboratories, Inc. ("USL"), by its undersigned counsel, brings this action for damages and equitable relief against Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Cadila Healthcare Ltd. ("Cadila," together with Zydus USA, "Zydus" and together with USL, the "Parties"), for breach of contract, and breach of the implied covenant of good faith and fair dealing, alleging as follows:

INTRODUCTION

1. This action stems from a settlement agreement dated January 12, 2017 (the "Agreement"), which USL and Zydus entered into before the United States District Court for the District of Delaware (the "Court"). [redacted]

[redacted]

2. As first applicant, Zydus was eligible for Hatch-Waxman Exclusivity, which operates to prevent a third party from gaining FDA approval of the same generic product for 180 days after the first approved generic enters the market. Zydus's eligibility was confirmed by the FDA.

3. USL brings this action after discovering that Zydus knowingly and voluntarily relinquished its eligibility for Hatch-Waxman Exclusivity—the entitlement to such Hatch-Waxman Exclusivity having been confirmed by the United States Food and Drug Administration ("FDA") pursuant to the Hatch-Waxman Act. Zydus voluntarily relinquished this right to allow Glenmark Pharmaceuticals Inc., USA ("Glenmark USA") and Glenmark Pharmaceuticals Ltd. ("Glenmark Ltd.," together with Glenmark USA, "Glenmark") to enter the topiramate extended-

[1] Capitalized terms not otherwise defined herein have the same meanings used in the Agreement, which is attached as **Exhibit A**.

release capsule market. Upon information and belief, Zydus received and continues to receive compensation from Glenmark in exchange for relinquishing its eligibility for Hatch-Waxman Exclusivity. [redacted] USL seeks monetary damages and injunctive relief from this Court to enforce the unambiguous terms of the Agreement and to remedy Zydus's willful breach of its obligations thereunder.

4. In 2016, USL filed an action captioned *Upsher-Smith Laboratories v. Zydus Pharmaceuticals (USA), Inc., et al.*, Civil Action No. 1:16-cv-00248-SLR (the "Patent Litigation Action"), against Zydus asserting infringement by Zydus of U.S. Patent Nos. 8,652,527, 8,889,190, and 9,101,545 (the "Asserted Patents")—listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for QUDEXY® XR—after Zydus filed an Abbreviated New Drug Application ("ANDA") seeking approval to market the Zydus Generic Products prior to the expiration of the Asserted Patents and containing a "Paragraph IV" certification to each of the Asserted Patents. In an effort to fully and finally settle the Patent Litigation Action, the Parties engaged in arms' length negotiations and were represented by counsel at all times during the negotiations. As a result of those discussions, the Parties settled the Patent Litigation Action on the terms and conditions set forth in the Agreement.

5. The bargain the Parties struck when they reached the Agreement was unambiguous: [redacted]

[redacted]

6. [redacted]

7. The Agreement is governed by Delaware law and provides for exclusive jurisdiction in this Court.

8. [redacted] As discussed in detail below, Zydus has breached this key provision.

9. Zydus has not yet secured FDA approval for the Zydus Generic Products and has not entered the generic topiramate extended-release market. In January 2019, the FDA found that Zydus had not forfeited its eligibility for the 180-day Hatch-Waxman Exclusivity. [redacted]

10. Indeed, Glenmark filed an ANDA seeking approval to market its generic topiramate extended-release capsules (the "Glenmark Generic Products") prior to the expiration of the Asserted Patents and U.S. Patent No. 9,555,005, and also containing a Paragraph IV certification for each of the patents. USL filed an action against Glenmark alleging infringement of the patents

in this Court. In connection with the resolution of that litigation, USL and Glenmark entered into a confidential non-exclusive license agreement (the "Glenmark Agreement"). Given Zydus's entitlement to Hatch-Waxman Exclusivity, Glenmark could not enter the market in any event.

11. All of that changed when, in November 2020, Zydus's Hatch-Waxman Exclusivity was inexplicably identified by the FDA on the Agency's Paragraph IV Patent Certifications List as "extinguished," which could only be the result of Zydus's voluntary relinquishment of its eligibility for Hatch-Waxman Exclusivity. Shortly thereafter, FDA granted Glenmark's ANDA final approval and Glenmark entered the topiramate extended-release market as the first generic in February 2021, quickly and significantly eroding USL's market share. [redacted]

12. [redacted]

[redacted]

13. [redacted] Tellingly, Zydus has refused to disclose the terms of its agreement with Glenmark to USL.

14. USL was, and will continue to be, harmed by Zydus's breach of the Agreement and the loss of the benefits of the Agreement. Through this Complaint, USL now seeks redress for Zydus's continuing breach of its contractual obligations under the Agreement.

THE PARTIES

15. Plaintiff Upsher-Smith Laboratories, LLC is a limited liability company organized and existing under the laws of the State of Minnesota and is the successor in interest to Upsher-Smith Laboratories, Inc., with its principal place of business at 6701 Evenstad Drive, Maple Grove, Minnesota 55369. It is a party to the Agreement.

16. Defendant Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Zydus USA is a wholly owned subsidiary of Cadila and is an agent or affiliate of Cadila. It is a party to the Agreement.

17. Defendant Cadila Healthcare Ltd. is a corporation organized and existing under the laws of India, with its principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad, 380015, Gujarat, India. It is a party to the Agreement.

18. Defendants are in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including within the District of Delaware.

NON-DEFENDANT CO-CONSPIRATORS

19. Co-conspirator Glenmark Pharmaceuticals Inc., USA is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07340. Upon information and belief, Glenmark USA is a wholly owned subsidiary of Glenmark Ltd. and is an agent or affiliate of Glenmark Ltd.

20. Co-conspirator Glenmark Ltd. is an entity organized and existing under the laws of India and having a principal place of business at B.D. Sawant Marg, Chakala, Andheri (East), Mumbai, Maharashta 400099.

21. Glenmark is in the business of manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including within the District of Delaware.

22. [redacted] In furtherance of the agreement with Glenmark, Zydus relinquished its eligibility for Hatch-Waxman Exclusivity, thereby forfeiting its right to be the first entrant into the market in favor of Glenmark [redacted]

23. Upon information and belief, the agreement between Zydus and Glenmark extends to the immediate-release capsule market in which they both compete—with Zydus ceding market share to Glenmark in violation of federal antitrust laws.

JURISDICTION AND VENUE

24. The Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332(a) because this action is between a citizen of a state and citizens of another state and of a foreign state, respectively, such that complete diversity of citizenship between the Parties exists, and the amount in controversy, exclusive of interest and costs, exceeds $75,000.

25. In addition, the Court has jurisdiction over the subject matter of this action because the Parties agreed that this Court has jurisdiction over the subject matter of the Agreement pursuant to the Stipulation of Dismissal and Order dated January 20, 2017 and entered by the Court in *Upsher-Smith Laboratories, Inc. v. Zydus Pharmaceuticals (USA) Inc., et al.*, C.A. No. 1:16-cv-00248-SLR.

26. Defendants are subject to the Court's personal jurisdiction, consistent with principles of due process and the Delaware Long Arm Statute, because Defendants voluntarily entered into the binding Agreement, [redacted]

27. Venue is proper pursuant to 28 U.S.C. §§ 1391(b) and (c). Venue is also proper in the District of Delaware because the Parties agreed [redacted]

STATEMENT OF FACTS

I. The Agreement

28. On March 11, 2014, the FDA approved USL's New Drug Application ("NDA") No. 205122 for QUDEXY® XR (topiramate) extended-release capsules in 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg strengths. QUDEXY® XR (topiramate) extended-release capsules were approved by the FDA for treatment of Partial Onset Seizures, Primary Generalized Tonic-Clonic Seizures, and Lennox-Gastaut Syndrome. As listed in the FDA's Orange Book, QUDEXY® XR (topiramate) extended-release capsules are covered by one or more claims of United States Patent Nos. 8,652,527, 8,889,190, 9,101,545, 9,555,005, and 10,363,224.

A. The Patent Litigation Action

29. On February 25, 2016, USL was notified that Zydus had submitted ANDA No. 208949 to the FDA, seeking approval to engage in the commercial manufacture, use and sale of the Zydus Generic Products prior to the expiration of the Asserted Patents. ANDA No. 208949, initially submitted to FDA on December 24, 2015, contains Paragraph IV certifications with respect to the Asserted Patents. Indeed, Zydus's ANDA 208949 was the first ANDA submitted to FDA seeking approval to market a generic version of QUDEXY® XR and containing a Paragraph IV certification to patent information listed in the Orange Book for QUDEXY® XR, thereby making Zydus a—in fact, the only—"first applicant" eligible for a period of 180-day exclusivity pursuant to the Hatch-Waxman Act.

30. In response to the Defendants' submission of ANDA No. 208949, on May 8, 2016, USL filed the Patent Litigation Action against Zydus, alleging that the Zydus Generic Products infringed the Asserted Patents.

31. The Parties engaged in arms'-length negotiations in an effort to fully and finally settle the Patent Litigation Action. Both Parties were represented by competent and experienced counsel during the negotiations.

32. Members of the pharmaceutical industry, the courts, as well as the public benefit when courts give effect to the intent and purposes of settlement agreements resolving patent infringement litigation, and federal courts have long recognized the importance of settlements in patent infringement litigation. "The importance of encouraging settlement of patent-infringement litigation, which all too frequently is complex, long-drawn-out, carried on through all the Courts, and even in different jurisdictions, cannot be overstated. If every patent-infringement case filed had to be tried the Courts would be clogged." *Schlegel Mfg. Co. v. U.S.M. Corp.*, 525 F.2d 775, 783 (6th Cir. 1975).

33. Consistent with public policy, the Parties entered into the Agreement on January 12, 2017 to fully and finally settle the Patent Litigation Action to: (i) avoid the significant legal expenses, uncertainty, and risk inherent in protracted patent-infringement litigation; (ii) permit the management of the Parties to focus on their respective companies rather than devoting their time and resources to the Litigation, and (iii) benefit the public in achieving a procompetitive final settlement of a patent litigation, which permits Zydus to market its generic products in the United States prior to the 2033 expiration of the Asserted Patents.

34. On January 20, 2017, the Court entered an Order dismissing the Parties' claims and counterclaims without prejudice, pursuant to the Stipulation and Order of Dismissal agreed upon among the Parties.

B. The Terms of the Agreement

35. [redacted]

36. [redacted]

37. [redacted]

38. [redacted]

39. [redacted]

40. [redacted]

41. [redacted]

II. Zydus's Efforts to Enter the Topiramate Extended-Release Capsule Market

42. Zydus's ANDA No. 208949 was the first substantially complete ANDA with a Paragraph IV certification for topiramate extended-release capsules in 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg strengths.

43. To incentivize generic drug manufacturers to challenge patents covering brand-name drugs, like QUDEXY® XR, the Hatch-Waxman Act provides 180 days of market exclusivity to the first ANDA applicant that challenges an Orange Book-listed patent on a brand-name drug with a Paragraph IV certification. *See* 21 U.S.C. §§ 355(j)(5)(B)(iv), (j)(5)(D)(iii)(II). The Hatch-Waxman Exclusivity precludes the FDA from approving another ANDA for the same drug during the 180-day exclusivity period. As the first ANDA filer, Zydus was eligible for Hatch-Waxman Exclusivity; Zydus's eligibility was confirmed by the FDA, which, as discussed below, did not initially grant Glenmark final approval for its product.

44. Zydus has not yet secured FDA approval for the Zydus Generic Products and has not entered the generic topiramate extended-release capsule market.

III. USL Learns that Zydus Has Breached the Agreement

A. Glenmark's Efforts to Enter the Topiramate Extended-Release Capsule Market

45. USL has consistently upheld its end of the bargain and satisfied its contractual obligations under the Agreement. [redacted]

46. On February 28, 2017, Glenmark submitted ANDA No. 210278 to the FDA, seeking approval to engage in the commercial manufacture, use and sale of the Glenmark Generic Products prior to the expiration of USL's patents. USL filed a complaint against Glenmark in the Court, alleging that the Glenmark Generic Products infringed the patents. The litigation was captioned *Upsher-Smith Laboratories, Inc. v. Glenmark Pharmaceuticals Limited, et al.*, C.A. No. 1:17-cv-00649-CJB (the "Glenmark Litigation"). On March 27, 2018, USL and Glenmark entered into a settlement and license agreement (the "Glenmark Settlement Agreement") to resolve the Glenmark Litigation. Consistent with its obligations under the Agreement, [redacted]

[redacted]

47. On January 22, 2019, the FDA tentatively approved Glenmark's ANDA No. 210278. After the FDA has determined that the first ANDA filer is entitled to the 180-day Hatch-Waxman Exclusivity, there are limited ways for a later ANDA filer to enter the market: (1) the first ANDA filer can get approval and launch; (2) the first ANDA filer can relinquish its Hatch-Waxman Exclusivity; (3) the FDA can determine that the first ANDA filer has forfeited their right to the Hatch-Waxman Exclusivity Period; or (4) the NDA holder can grant the later ANDA filer rights to market an authorized generic of the brand drug. *See* 21 U.S.C. § 355(j)(5)(D). The FDA did not grant final approval of Glenmark's ANDA No. 210278 because:

> [p]rior to the submission of your ANDA, another applicant or applicants submitted a substantially complete ANDA providing for Topiramate Extended-Release Capsules, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg, and containing a paragraph IV certification. Your ANDA will be eligible for final approval on the date that is 180 days after the commercial marketing date identified in section 505(j)(5)(B)(iv) of the FD&C Act. (emphasis added)

Thus, Glenmark's ANDA No. 210278 was not eligible for final approval until 180 days after Zydus began commercial marketing of its product.

48. In late 2020, Glenmark approached USL to request an earlier market entry date for the Glenmark Generic Products. [redacted]

B. Zydus Breaches its Obligations Under Section 2.4(c) of the Agreement

49. As of January 22, 2019, it was the FDA's position that Zydus was eligible for 180 days of generic marketing exclusivity pursuant to the Hatch-Waxman Act [redacted]

50. But according to the FDA's November 17, 2020 Paragraph IV Patent Certifications List, Zydus relinquished its eligibility for Hatch-Waxman Exclusivity such that it was identified on the List as "extinguished," thereby clearing the path for FDA to convert its initially conferred tentative to final approval of Glenmark's ANDA No. 210278.

51. Upon information and belief, Zydus took this action in furtherance of an agreement Zydus entered into with Glenmark that would allow Glenmark the ability to be the first generic to enter the topiramate extended-release market. Upon information and belief, Zydus received and continues to receive monetary compensation from Glenmark in exchange for clearing a path for Glenmark to receive final approval from the FDA and enter the topiramate extended-release capsule market early. Upon information and belief, the agreement between Zydus and Glenmark extends to the immediate-release capsule market—with Zydus ceding market share to Glenmark in violation of U.S. antitrust laws.

52. [redacted]

53. By relinquishing its eligibility for Hatch-Waxman Exclusivity and allowing Glenmark to enter the topiramate extended-release capsule market as the first generic manufacturer, [redacted]

54. Shortly after Zydus voluntarily relinquished its eligibility for Hatch-Waxman Exclusivity, Glenmark amended its ANDA No. 210278, indicating to the FDA that Zydus had relinquished its eligibility for Hatch-Waxman Exclusivity and requesting Final Approval of its product. On the basis of Glenmark's amendment, the FDA issued a letter converting the January

22, 2019 Tentative Approval of Glenmark's ANDA No. 210278 into a Final Approval on February 1, 2021.

55. [redacted]

56. [redacted]

C. Glenmark and Zydus Reap the Benefits of the Breach and Glenmark's First Entry Into the Market, [redacted]

57. During the first week of February 2021, Glenmark began the marketing, sale and distribution of the Glenmark Generic Products throughout the United States and [redacted]

58. Upon information and belief, as of the date of this filing, Glenmark has sold approximately 758,000 units of the Glenmark Generic Products, earning approximately $8.4 million in revenue.

59. Upon information and belief, Zydus received, is receiving, or will receive compensation, whether monetary or non-monetary, from Glenmark pursuant to an agreement between Zydus and Glenmark that allowed Glenmark to enter the topiramate extended-release capsule market as the first generic manufacturer [redacted]

60. As of the date of this filing, Zydus has not secured Final FDA Approval for its ANDA No. 208949.

61. As of the date of this filing, Zydus has not entered the market for generic topiramate extended-release capsules and, but for its actions, no other generic product should have entered this market.

62. USL has been significantly damaged and continues to be significantly damaged by Zydus's actions [redacted]

CLAIMS FOR RELIEF

COUNT ONE:
Breach of Contract (Damages)

63. Plaintiff repeats and realleges all the foregoing allegations in all of the preceding paragraphs of this Complaint as if they were set forth fully herein.

64. As described above, USL and Zydus mutually entered into the Agreement to fully and finally settle the action styled as *Upsher-Smith Laboratories, Inc. v. Zydus Pharmaceuticals (USA) Inc., et al.,* C.A. No. 1:16-cv-00248-SLR then pending in this Court.

65. The Agreement is a valid, binding, and enforceable contract.

66. USL performed all of its obligations under the Agreement.

67. [redacted]

68. [redacted]

69. [redacted]

70. [redacted]

71. [redacted]

COUNT TWO:
Breach of Contract (Specific Performance)

72. Plaintiff repeats and realleges all the foregoing allegations in all of the preceding paragraphs of this Complaint as if they were set forth fully herein.

73. As described above, USL and Zydus mutually entered into the Agreement to fully and finally settle the action styled as *Upsher-Smith Laboratories, Inc. v. Zydus Pharmaceuticals (USA) Inc., et al.*, C.A. No. 1:16-cv-00248-SLR then pending in this Court.

74. The Agreement is a valid, binding, and enforceable contract.

75. USL performed all of its obligations under the Agreement.

76. USL remains willing and able to continue to perform its obligations under the Agreement.

77. [redacted].

78. [redacted]

79. [redacted]

80. To the extent that certain of the damages for breach of contract are not easily ascertainable— [redacted] — USL has no adequate remedy at law.

81. USL is entitled to an Order compelling Zydus, to specifically perform all of its obligations under the Agreement, [redacted] Specifically, USL is entitled to an Order compelling Zydus to: (i) void the agreement with Glenmark under which Zydus agreed to take actions to allow Glenmark to enter the topiramate extended-release capsule market as the first generic, [redacted]

COUNT THREE:
Breach of the Implied Covenant of Good Faith and Fair Dealing
(In The Alternative)

82. USL pleads this cause of action for breach of the implied duty of good faith and fair dealing in the alternative to Counts One and Two herein.

83. Plaintiff repeats and realleges all the foregoing allegations in all of the preceding paragraphs of this Complaint as if they were set forth fully herein.

84. As described above, USL and Zydus mutually entered into the Agreement to fully and finally settle the action styled as *Upsher-Smith Laboratories, Inc. v. Zydus Pharmaceuticals (USA) Inc., et al.*, C.A. No. 1:16-cv-00248-SLR then pending in this Court.

85. The Zydus Settlement and License Agreement is a valid, binding, and enforceable contract.

86. USL performed all of its obligations under the Agreement.

87. USL remains willing and able to continue to perform its obligations under the Zydus Settlement and License Agreement.

88. [redacted]

89. Contracts are subject to an implied covenant of good faith and fair dealing that all parties will act in good faith and with reasonable efforts to perform their contractual duties—both explicit and fairly implied—and refrain from arbitrary or unreasonable conduct that has the effect of preventing the other party from receiving the benefits of its bargain.

90. [redacted]

91. [redacted]

92. Zydus's arbitrary and unreasonable conduct frustrated the overarching purpose of the Agreement and had the effect of preventing USL from receiving the full benefits of the Agreement.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff USL respectfully requests the following relief:

(1) A judgment that Zydus has breached [redacted] the Agreement;

(2) Compensatory damages, including without limitation for loss of the benefits accruing to USL as an NDA holder under the Hatch-Waxman Act, [redacted]

(3) In the alternative, a judgment that Zydus has breached the implied covenant of good faith and fair dealing arising in connection with its obligations under the Agreement;

(4) Compensatory damages, including without limitation for loss of the benefits accruing to USL as an NDA holder under the Hatch-Waxman Act, [redacted] or specific performance, as well as any other appropriate relief, arising out of Zydus's breach of the implied covenant of good faith and fair dealing arising in connection with its obligations under the Agreement,

(5) USL's reasonable costs and expenses in this action; and

(6) Such other and further legal and equitable relief as to the Court may deem just and proper.

Dated: August 4, 2021

MCCARTER & ENGLISH, LLP

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EXHIBIT A

The January 12, 2017
Settlement and License Agreement between
Upsher-Smith Laboratories, Inc. and
Zydus Pharmaceuticals USA and
Cadila Healthcare Limited

IS REDACTED IN ITS ENTIRETY